IN THE CIRCUIT COURT OF JACKSON COUNTY, MISSOURI
AT INDEPENDENCE

MARY PLUBELL, on behalf of herself and all others similarly situated,	)	
Plaintiff,	)	Case No.: 04CV235817
vs.	)	Division: 5
MERCK & CO., INC., a New Jersey corporation,	)	
Defendant.	)	**JURY TRIAL DEMANDED**

FIRST AMENDED CLASS ACTION PETITION

Plaintiff Mary Plubell, individually and on behalf of all others similarly situated, through her attorneys, alleges the following upon information and belief, except as to the allegations that pertain to herself, which are based upon personal knowledge:

NATURE OF THE ACTION

1. Plaintiff brings this action on her own behalf and as representative of a class of persons consisting of all Missouri residents who were prescribed the drug VIOXX® ("Vioxx"), or their estates, administrators or other legal representatives, heirs or beneficiaries.

2. Plaintiff brings this action individually and as class representative to recover damages for violations of Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010 *et seq.*, for economic relief against Defendant Merck & Co., Inc., which tested, marketed, distributed, promoted and sold Vioxx.

3. Plaintiff, on behalf of herself and the putative class, seeks a refund for monies paid as a result of her purchase of Vioxx.

THE PARTIES

4. Plaintiff is, and was at all relevant times, a citizen of Blue Springs, Jackson County, Missouri. Plaintiff purchased and consumed Vioxx within the jurisdiction of this Court.

5. Defendant is a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey. Defendant is a pharmaceutical company that conducts business throughout the nation, including Independence, Missouri.

JURISDICTION AND VENUE

6. This Court has personal jurisdiction over Defendant pursuant to § 506.500 R.S. Mo. in that Defendant transacts business within the state of Missouri.

7. Venue is proper in this Court pursuant to § 508.040 R.S. Mo., because Plaintiff's cause of action accrued in Jackson County, Missouri.

8. The total amount in controversy as to the plaintiff and each individual member of the proposed class alleged herein does not exceed seventy-four thousand nine hundred ninety-nine dollars ($74,999.00), including treble damages, interest and costs. Plaintiff specifically disclaims any relief, whether in law or in equity, in excess of $74,999. In addition, neither the Plaintiff nor any member of the Plaintiff's Class assert any federal question.

FACTUAL BACKGROUND

9. Vioxx is the brand name of rofecoxib, one of a class of drugs called "prostaglandins," which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle pain. Prostaglandins are COX (cyclooxygenase) inhibitors; COX enzymes metabolize arachidonic acid to produce prostaglandins.

10. Vioxx is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

11. Defendant Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

12. Defendant Merck also submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for oral suspension, at doses of 12.5 mg/ml and 25 mg/ml, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

13. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the "NDA") for rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea.

14. Defendant launched Vioxx in the United States in 1999 and has marketed and sold in it more than 80 countries. Worldwide sales of Vioxx in 2003 were $2.5 billion.

15. At the time the drug was approved by the FDA the labeling for rofecoxib stated, in the section entitled "Special Studies -- Upper Endoscopy in Patients with

Osteoarthritis," "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo."

16. The "Warnings" section of the labeling for rofecoxib, at the time the drug was approved by the FDA, contains a section, "Gastrointestinal (GI) Effects -- Risk of GI Ulceration, Bleeding, and Perforation."

17. Defendant Merck submitted sNDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the sNDA, Defendant Merck performed the Vioxx GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

18. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking naproxen 1000 mg/day," and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

19. In March 2000, the results from the Vigor study were released to Merck. These results showed that the Vioxx group had more blood clot related problems than the Naproxen group. In fact, the heart attack rate was four to five times as high in the Vioxx group as it was in the Naproxen group.

20. The results were such that Merck's research chief, Dr. Scolnick wrote in a March 9, 2000 email that the cardiovascular events "are clearly there."

21. In a press release that same month, Merck failed to disclose any of Dr. Scolnick's conclusion that a "mechanism-based" problem existed with Vioxx.

22. In industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and stroke. Not only did Merck do nothing to further accurately publish these studies, or warn consumers, but it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, Pharmacy Today, *Spin War Aside, Lessons Emerge From COX-2 Trials,* in August 2000, page 3.

23. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial stability to the detriment of its consumers. As a result of Merck's scheme, it reaped more than $2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market.

24. Merck continued to profit from its scheme by withholding information from Plaintiff, the consuming public, and the health care industry. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine in which it knowingly downplayed and/or withheld the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.

25. On or about August 29, 2001, the Journal of the American Medical Association (JAMA) published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukhisjee, et al., showing what Merck had concealed that the relative risk of developing a "confirmed adjudicated thrombotic cardiovascular event" (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Merck's trials, including VIGOR, at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirin-indicated patients. *See* Mukhisjee, D., et al., *Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors,* J.A.MA. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users.

26. In the JAMA study, the authors stated that "by decreasing PGI2 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PGI2, potentially leading to an increase in thrombotic cardiovascular events." *Id.* at 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lomnicka, M., *Why Do Cyclo-Oxygenase-2Iinhibitors Cause Cardiovascular Events?,* J.A.C.C., 39:3, Feb. 6, 2002. This is further supported

by studies completed at the University of Pennsylvania. Cheng, *Y.*, et al., *Role of Prostacyclin in the Cardiovascular Response to Thromboxane A2*, Journal of Science, V. 296:539-541, Apr. 19, 2002.

27. On September 17, 2001, Thomas W. Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to Raymond V. Gilmartin, President and CEO of Defendant Merck, relating to "promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets."

28. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

> Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

29. The eight (8) page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following **"Conclusions and Requested Actions:"**

> The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx / Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.
>
> Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed

response to the issues raised in this Warning Letter on or before October 1, 2001.
This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

> Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
>
> Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.
>
> A written statement of your intent to comply with "1" and "2" above.

30. On April 11, 2002, the FDA approved a supplemental application for the use of Vioxx (rofecoxib) for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

31. The revised labeling further states that the administration of Vioxx 50 mg, was associated with a higher incidence of gastrointestinal symptoms.

> Clinical Studies in "OA and BA with VIOXX 50 mg (Twice the highest dose recommended for chronic use)
>
> In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as VIOXX 50 mg, VIOXX 50 mg OD was associated with a higher incidence of gastrointestinal symptoms (abdominal pain, epigastric pain, heartburn, nausea and vomiting), lower extremity edema, hypertension, serious* adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 mg (see DOSAGE AND ADMINISTRATION).

32. Further, the "Dear Doctor" letter, approved in conjunction with the revisions to the Vioxx labeling, outlines the changes to the Vioxx labeling.

33. The revised "Patient Information" sheet does not add any information about the results of the VIGOR study.

34. The "Patient Information" sheet is the only written document that is provided to a patient for whom Vioxx is prescribed.

35. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that Vioxx may cause serious side effects, Defendant Merck has concealed and/or downplayed the dangers associated with Vioxx.. In its 2001 Annual Report, for example, Defendant Merck stated:

> The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to *Vioxx*. . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

36. Additionally, internal Merck marketing documents, provided field personnel, responsible for Vioxx, with an "obstacle handling guide" that instructed them on how to address concerns of doctors. These documents proposed that the drug representatives "dodge" the doctors concerns and tell doctors that for cardiovascular issues, Vioxx was "not a substitute for aspirin."

37. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, the Defendant fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, **VIOXX,** ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAIR, drove Merck's performance for the year

and created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.

"Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. **VIOXX,** a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **VIOXX** has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, **VIOXX** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **VIOXX** achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter.

A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which **VIOXX** reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **VIOXX** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

38. Despite the foregoing, Defendant Merck continued to represent to consumers that Vioxx was safe, and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug.

39. On September 30, 2004, after denying safety concerns for years, Defendant announced a voluntary withdrawal of Vioxx from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients taking Vioxx.

CLASS ACTION ALLEGATIONS

40. Plaintiff brings this class action pursuant to Missouri Rule of Civil Procedure 52.08 on behalf of herself and the following class of similarly situated persons: all Missouri residents who purchased Vioxx for personal or family use.

41. Excluded from the Class are Defendant, including any parent, subsidiary, affiliate or controlled person of Defendant; Defendant's officers, directors, agents or employees; the judicial officers assigned to this litigation; and members of their staffs and immediate families. Also excluded from the class are those claiming they have suffered a personal injury as a result of taking Vioxx.

42. The proposed Class meets all requirements for class certification. The Plaintiff Class satisfies the numerosity standards. The Class is believed to number in the thousands of persons in the state of Missouri. As a result, joinder of all Class Members in a single action is impracticable. Class Members may be informed of the pendency of this Class Action by published and broadcast notice.

43. There are questions of fact and law common to the Class which predominate over any questions affecting only individual members. The questions of law and fact common to the Class arising from Defendant's actions include, without limitation, the following:

(a) whether, in marketing and selling Vioxx, Defendant failed to disclose the dangers and risks to the health of persons ingesting the drug;

(b) whether Defendant falsely and fraudulently misrepresented in its advertisements, promotional materials and other materials, among other things, the safety, potential side effects and efficacy of Vioxx;

(c) whether Defendant failed to warn adequately of the adverse effects of Vioxx;

(d) whether Defendant designed and manufactured a drug that was dangerously defective because its use leads to serious adverse health effects, including cardiovascular events;

(e) whether Defendant knew or should have known that the use of Vioxx leads to serious adverse health effects;

(f) whether Defendant adequately tested Vioxx prior to distribution and sales in the market place;

(g) whether Defendant continued to manufacture, market, distribute, and sell Vioxx notwithstanding its knowledge of the drug's dangerous nature;

(h) whether Defendant knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Vioxx from government regulators, the medical community and/or the consuming public;

(i) whether Defendant's conduct violated Missouri's Merchandising Practices Act.

44. The questions set forth above predominate over any questions affecting only individual persons, and a Class Action is superior with respect to considerations of consistency, economy, efficiency, fairness and equity, to other available methods for the fair and efficient adjudication of this controversy.

45. A Class Action is the appropriate method for the fair and efficient adjudication of this controversy. The presentation of separate actions by individual Class Members could create a risk of inconsistent and varying adjudications, establish incompatible standards of conduct for Defendant, and/or substantially impair or impede the ability of Class Members to protect their interests.

46. The Plaintiff is an adequate representative of the Class because she is a member of the Class and her interests do not conflict with the interests of the members of the Class she seeks to represent. The interests of the members of the Class will be fairly and adequately protected by the Plaintiff and her undersigned counsel, who have extensive experience prosecuting complex class action litigation.

47. Plaintiff seeks a refund of monies paid as a result of their purchase of Vioxx, that occurred following Defendant's wrongful and improper conduct in

connection with the manufacture, marketing, distribution, testing, promotion, labeling and/or selling of Vioxx.

48. Plaintiff specifically excludes from this class action any damages, losses, or other relief of any kind arising from the personal injuries suffered by those class members diagnosed with the various diseases caused by Vioxx. This class action seeks only the economic relief requested herein to which class members are entitled under the Missouri Merchandising Practices Act.

49. Maintenance of this action as a class action is a fair and efficient method for the adjudication of this controversy. It would be impracticable and undesirable for each member of the Class who suffered harm to bring a separate action. In addition, the maintenance of separate actions would place a substantial and unnecessary burden on the courts and could result in inconsistent adjudications, while a single class action can determine, with judicial economy, the rights of all Class Members.

50. Notice can be provided to Class Members by using techniques and forms of notice similar to those customarily used in other drug-related cases and complex class actions.

CLAIM FOR RELIEF

COUNT I

VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT

51. Plaintiff incorporates by reference the allegations in all paragraphs of this Petition as though fully set forth in this paragraph.

52. The acts and practices engaged in by Defendant, and described herein, constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, Mo. Ann. Stat. §§ 407.010 *et seq.*

53. Defendant engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution or advertisement of Vioxx in violation of Mo. Rev. Stat. § 407.020.

54. Plaintiff purchased Vioxx, a product that was falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act and as a result Plaintiff suffered economic damages in that the product she and other class members purchased was worth less than the product they thought they had purchased had Defendant's representations been true.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter judgment against Defendant and in favor of Plaintiff and award the following relief:

(a) Certification of the proposed Class;

(b) Return of all purchase costs Plaintiff paid for Vioxx but in no event in excess of $74,999 per Plaintiff; and

(c) Attorneys' fees and those costs available under the law, but only to the extent individualized relief does not exceed $74,999.

Dated: September 1, 2005

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was served, via facsimile and U.S. Mail, postage prepaid, this 1 day of September 2005, on:

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SSHW-0408-35651.1